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Raybin et al.

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(54) **GRASPER NEEDLE CLOSURE DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 156 days.

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(22) Filed: **Jun. 21, 2017**

(65) **Prior Publication Data**

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(51) **Int. Cl.**

A61B 17/04	(2006.01)
A61B 17/00	(2006.01)
A61B 17/06	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/0401*** (2013.01); ***A61B 17/0057*** (2013.01); *A61B 17/0487* (2013.01); *A61B 2017/00663* (2013.01); *A61B 2017/0409* (2013.01); *A61B 2017/0417* (2013.01); *A61B 2017/0462* (2013.01); *A61B 2017/0464* (2013.01); *A61B 2017/061* (2013.01); *A61B 2017/06176* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/0487; A61B 17/0401; A61B 2017/0409; A61B 2017/0417; A61B 2017/2926; A61B 2017/2945; A61B 17/062; A61B 17/29; A61B 17/0469

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2003/0149447	A1*	8/2003	Morency	A61B 17/06166 606/228
2004/0122473	A1*	6/2004	Ewers	A61B 17/00234 606/222

(Continued)

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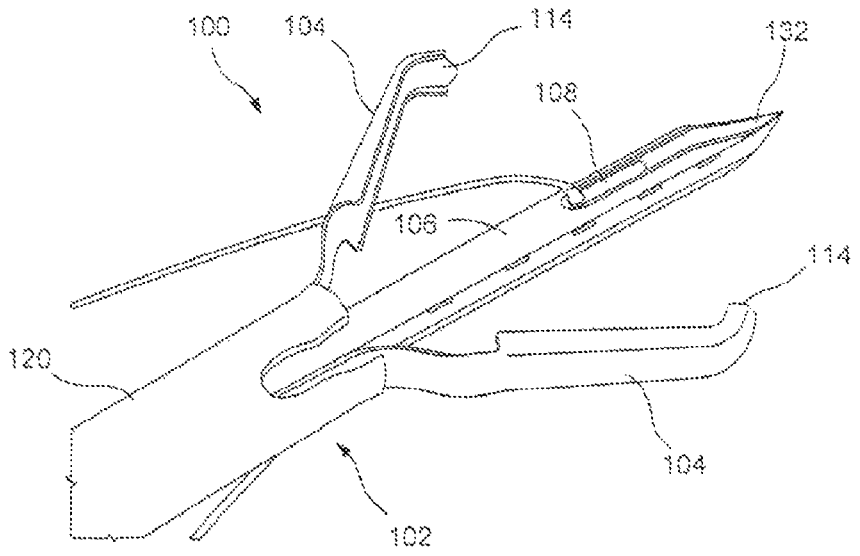
(57) **ABSTRACT**

A device for treating a tissue defect including a grasper including a pair of arms movable between a tissue receiving configuration and a tissue gripping configuration, a needle extending longitudinally from a proximal end to a distal end and including a first lumen extending longitudinally therethrough, the needle slidably received between the arms so that the needle is movable between a non-extended configuration, in which the distal end of the needle is proximal the distal ends of the arms, and an extended configuration, in which the distal end of the needle is distal of the distal end of the arms, and a first suture element slidably housed within the first channel and deployable therefrom to be anchored in a first target tissue into which it is inserted, the first suture element including a first cross member attached to a distal end of a first suture.

14 Claims, 9 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

2006/0264699	A1*	11/2006	Gertner	G06F 17/277 600/37
2009/0312602	A1*	12/2009	Sakamoto	A61B 17/0401 600/104
2010/0036395	A1*	2/2010	Miller	A61B 17/0401 606/139
2015/0374358	A1*	12/2015	Suzuki	A61B 17/0401 606/145

* cited by examiner

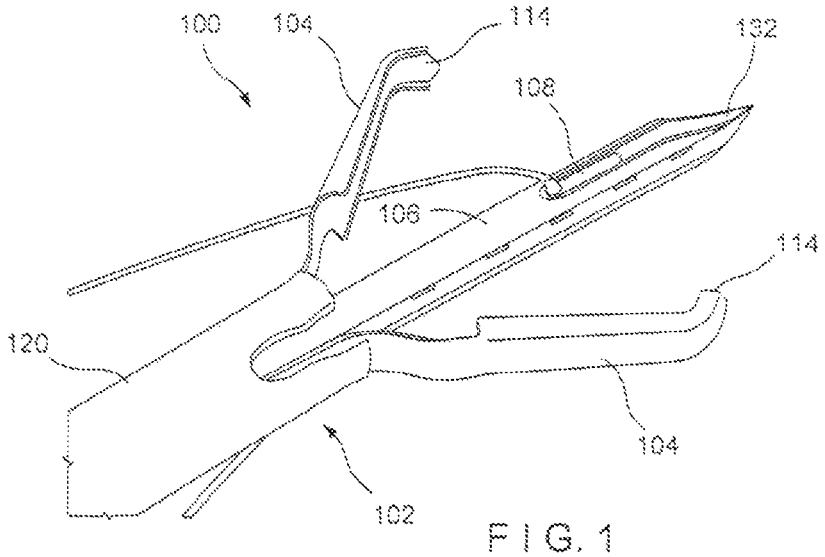


FIG. 1

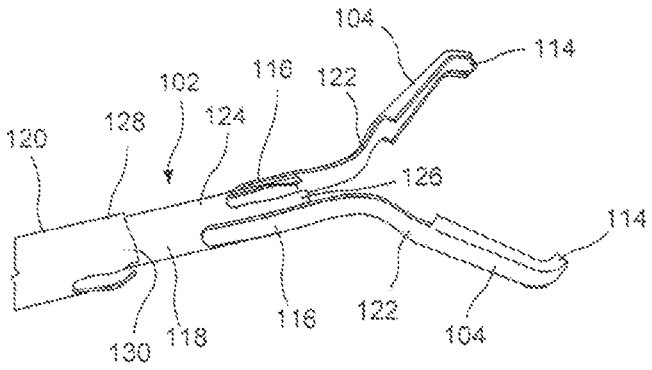


FIG. 2

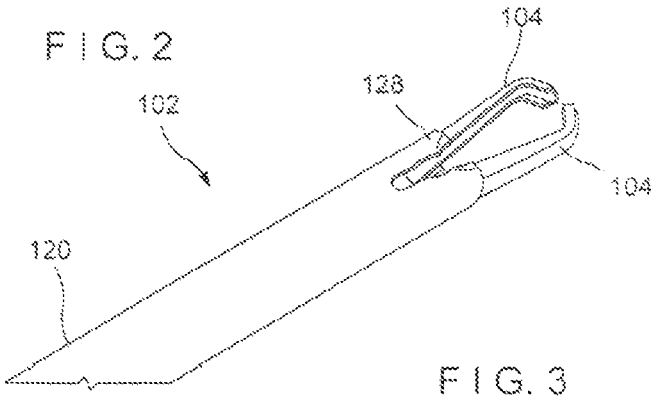


FIG. 3

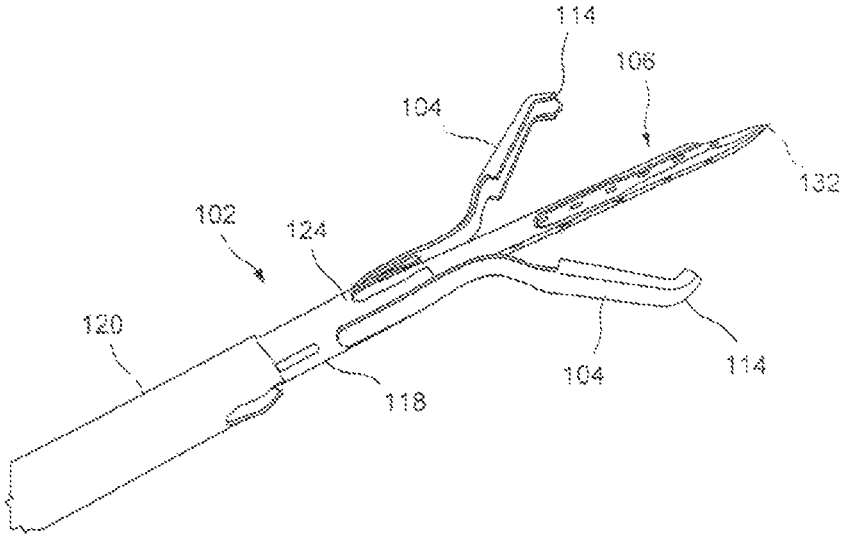
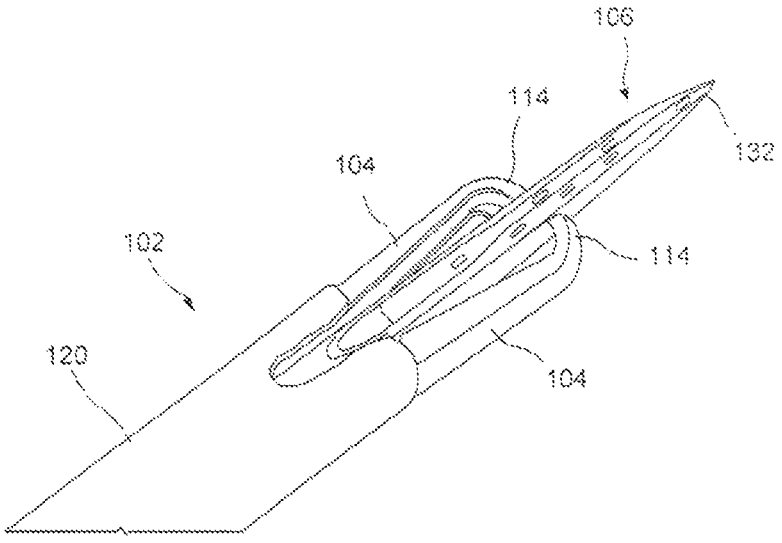

114
106
104
132
102
124
120
104
114
118

FIG. 4


106
114
132
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102
114
120
104

FIG. 5

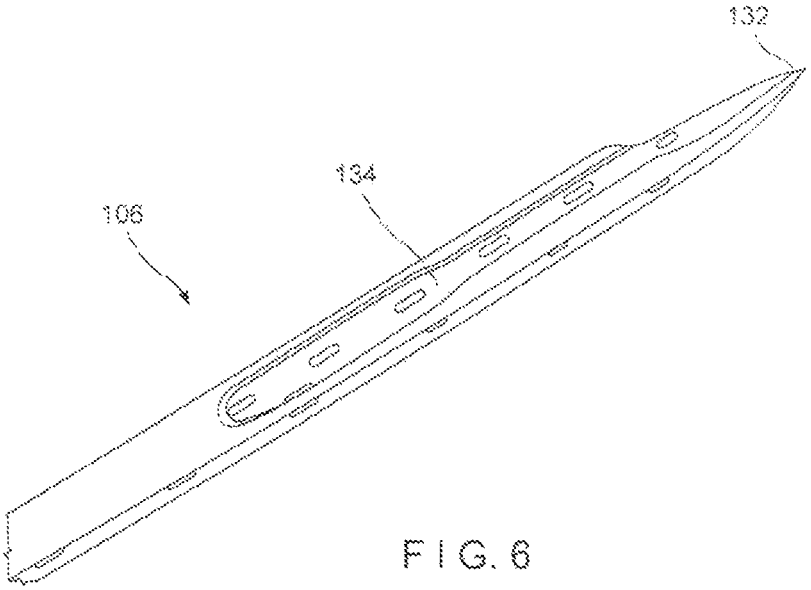


FIG. 6

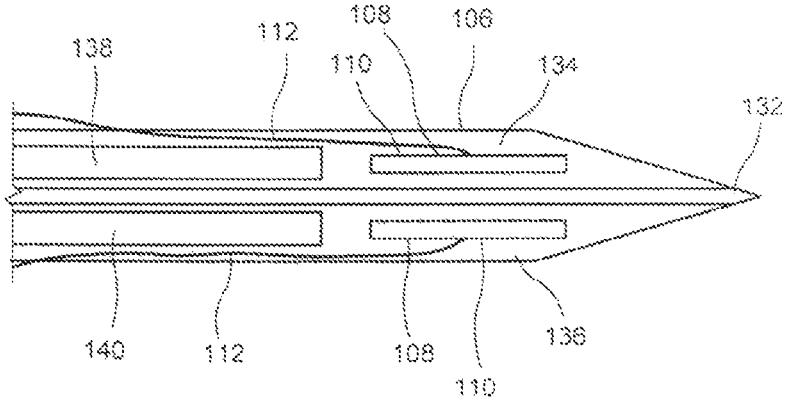


FIG. 7

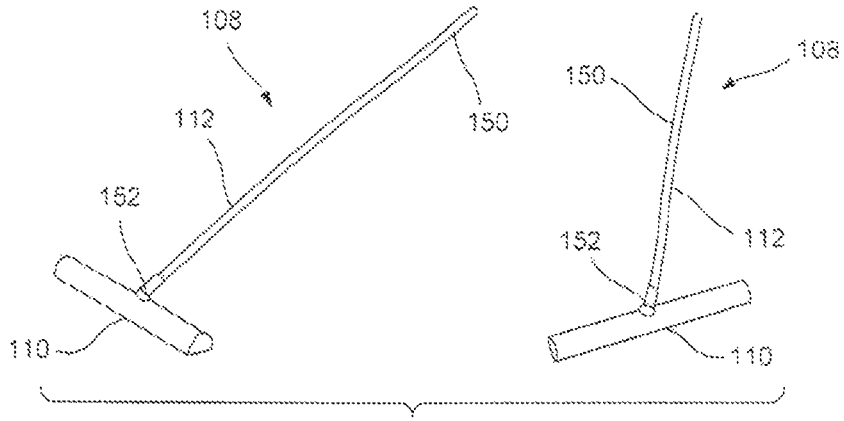


FIG. 8

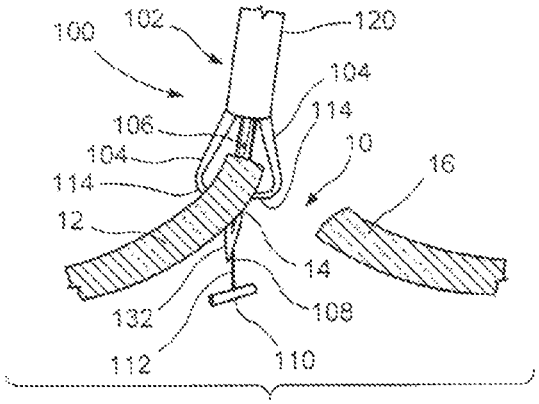


FIG. 9

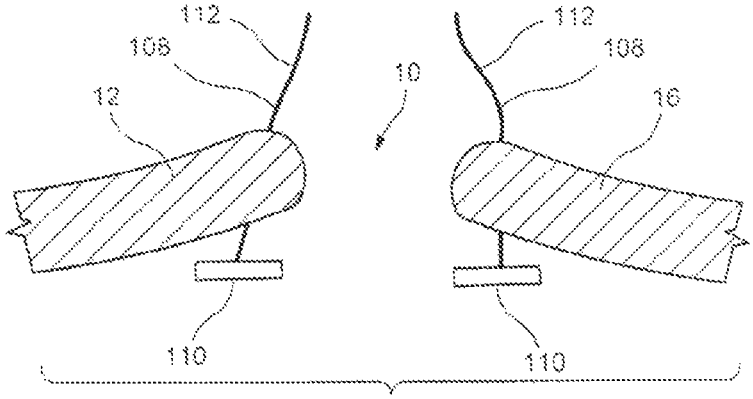


FIG. 10

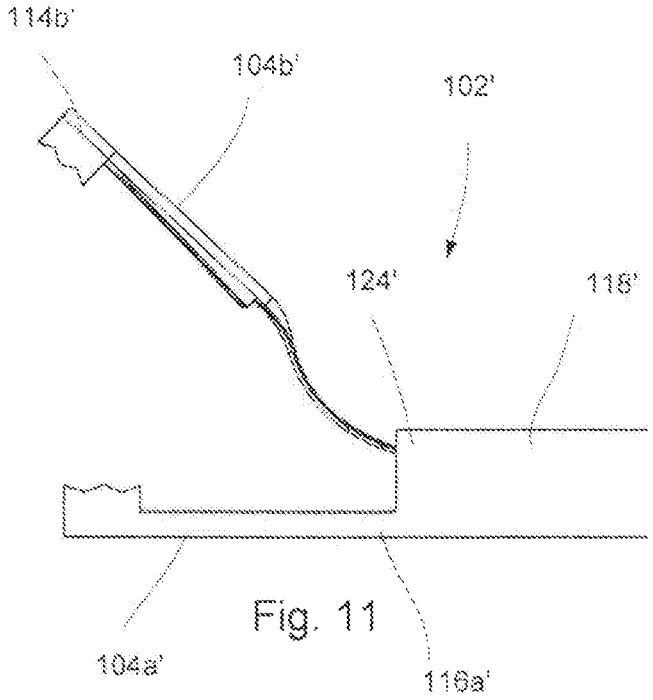
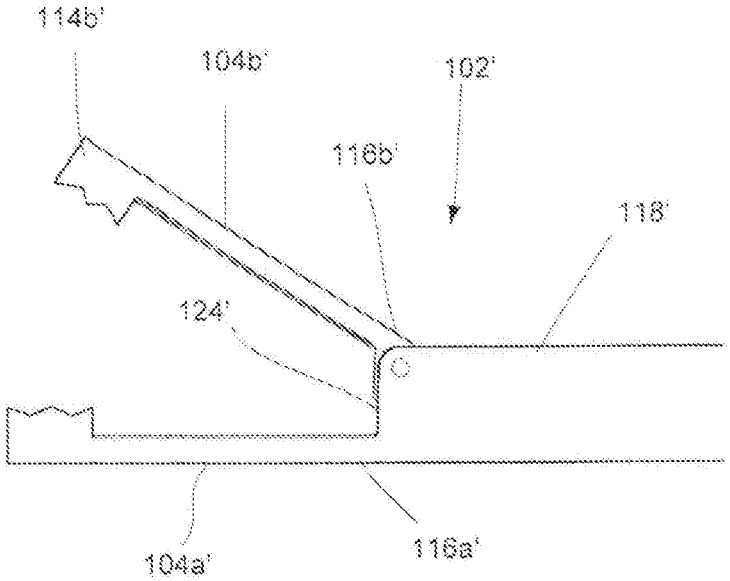

114b'
104b'
102'
124'
118'
104a'
116a'

Fig. 11


114b'
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118'
124'
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116a'

Fig. 12

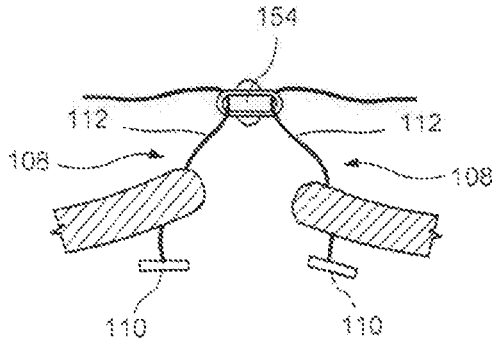

FIG. 13

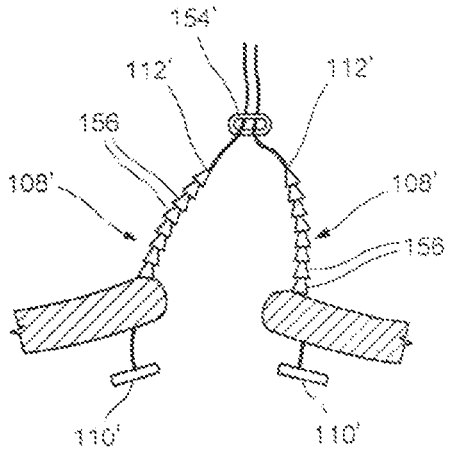

FIG. 14

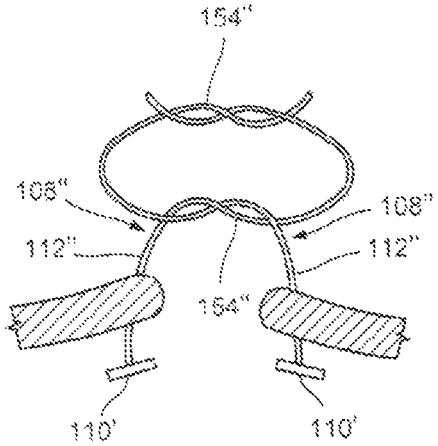

FIG. 15

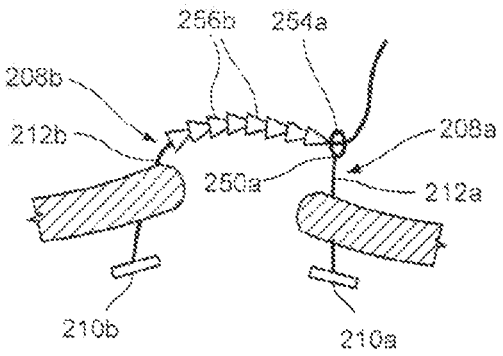

FIG. 16

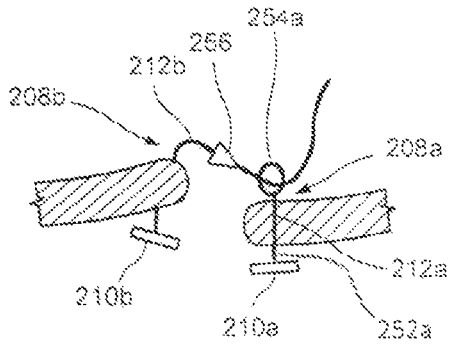

FIG. 17

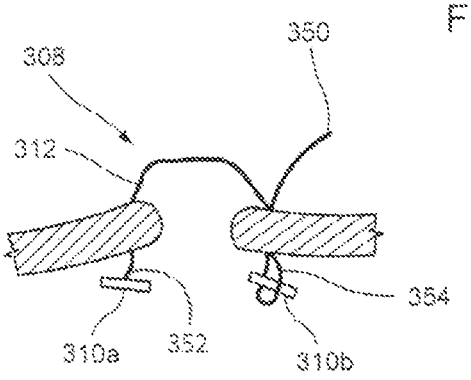

FIG. 18

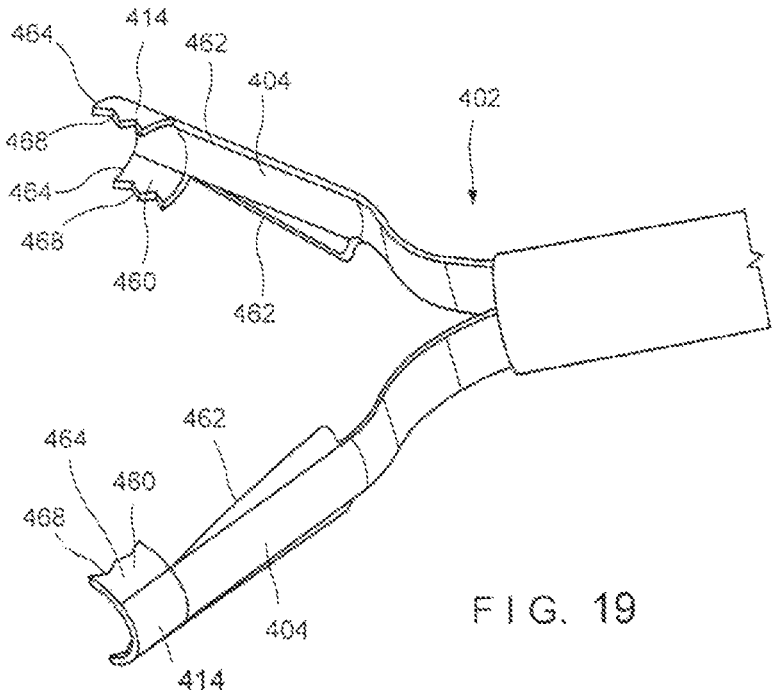
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FIG. 19

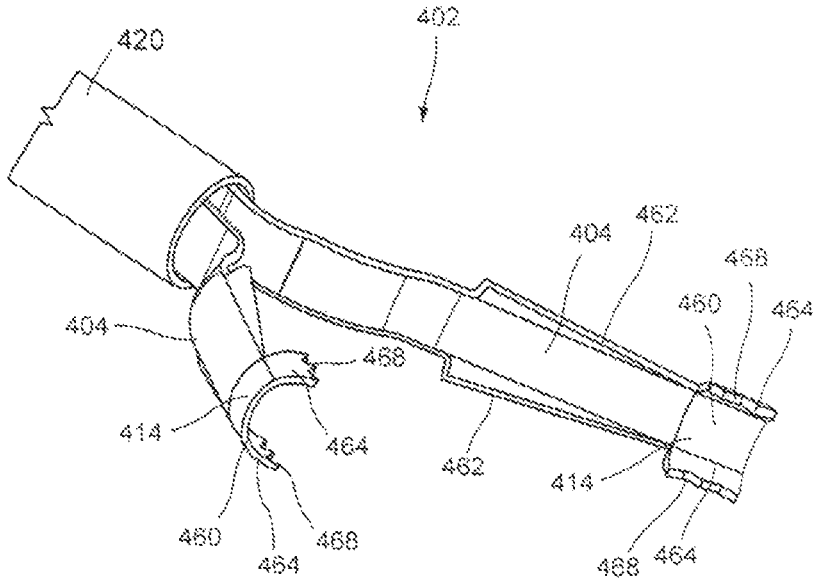
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FIG. 20

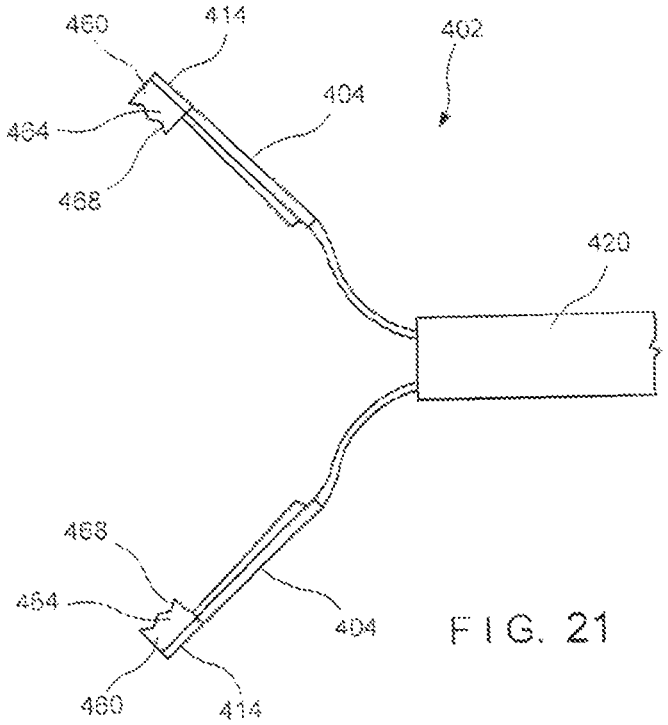
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FIG. 21

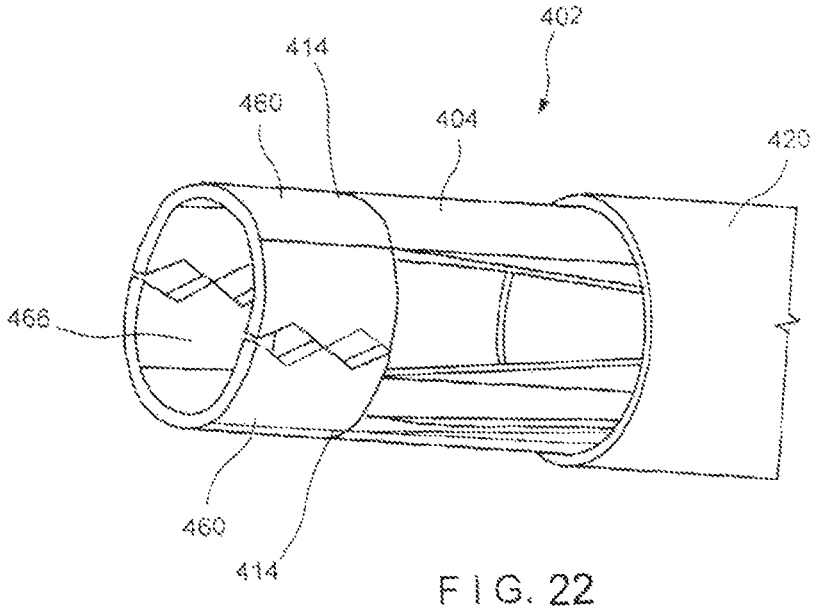
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FIG. 22

GRASPER NEEDLE CLOSURE DEVICE

PRIORITY CLAIM

The present disclosure claims priority to U.S. Provisional Patent Application Ser. No. 62/369,320 filed Aug. 1, 2016; the disclosure of which is incorporated herewith by reference.

BACKGROUND

Physicians have become more willing to perform more aggressive interventional and therapeutic endoscopic procedures including, for example, removal of larger lesions (e.g., cancerous masses), tunneling under mucosal layers in the gastro-intestinal (GI) tract to treat tissues below the mucosa, full thickness removal of tissue, inserting devices through the GI tract and then penetrating the GI organ to treat tissue outside the GI tract, and endoscopic treatment/repair of post-surgical issues (e.g., post-surgical leaks, breakdown of surgical staple lines, anastomotic leaks). These procedures may increase the risk of perforating the wall of the GI tract, or may require closure of the GI tract wall as part of the procedure. Endoscopic closure reduces cost and may reduce the trauma and inconvenience associated with these procedures. However, conventional tissue closure devices may be insufficient to close certain perforations.

SUMMARY

The present disclosure relates to a device for treating a tissue defect, comprising a grasper including a pair of arms movable between a tissue receiving configuration, in which distal ends thereof are separated from one another to receive tissue therebetween, and a tissue gripping configuration, in which the distal ends thereof are moved toward one another to grip tissue therebetween, a needle extending longitudinally from a proximal end to a distal end and including a first lumen extending longitudinally therethrough, the needle slidably received between the arms so that the needle is movable between a non-extended configuration, in which the distal end of the needle is proximal the distal ends of the arms, and an extended configuration, in which the distal end of the needle is distal of the distal end of the arms, and a first suture element slidably housed within the first channel and deployable therefrom to be anchored in a first target tissue into which it is inserted, the first suture element including a first cross member attached to a distal end of a first suture.

In an embodiment, the grasper may further include an inner sleeve extending from a proximal end to a distal end and including a channel extending therethrough, proximal ends of the arms connected to the distal end of the inner sleeve on opposing sides thereof.

In an embodiment, the arms may be biased toward the tissue receiving configuration.

In an embodiment, the grasper may further include an outer sleeve extending from a proximal end to a distal end and including a channel extending therethrough, the arms slidably movable relative to the outer sleeve to be moved between the tissue receiving configuration and the tissue gripping configuration, an interior surface of the outer sleeve constraining the arms toward the tissue gripping configuration when the arms are drawn into the channel of the outer sleeve.

In an embodiment, the device may further comprise a second suture element, the second suture element including a second cross member attached to a distal end of a second suture.

In an embodiment, the device may further comprise a cinch slidable along a length of the first and second sutures to move the first and second cross members toward one another and approximate the first and second target.

In an embodiment, at least one of the first and second sutures may include one of teeth and barbs along a length thereof.

In an embodiment, another one of the first and second sutures may include an opening for engaging one of the teeth and barbs.

In an embodiment, the needle may further comprise a second lumen extending longitudinally therethrough, the second suture element received within the second lumen of the needle.

In an embodiment, one of the first and second lumens may be open to an exterior of the needle along a length thereof.

In an embodiment, the first suture element may be movable between an insertion configuration, in which the first cross member is substantially aligned along a length of the first suture, and an anchoring configuration, in which first cross member extends transverse to a length of the first suture.

In an embodiment, the distal ends of the grasper may include distal tips extending laterally inward toward one another to grip the target tissue therebetween.

In an embodiment, the distal ends of the graspers may include a gripping structure which, when the arms are in the tissue gripping configuration, form an opening extending therethrough so that the needle, in the extended configuration, passes through the opening.

In an embodiment, gripping edges of the distal ends of the arms may include one of teeth, spikes and protrusions for gripping the target tissue received between the distal ends of the arms.

The present disclosure also relates to a device for approximating edges of a tissue defect, comprising a grasper including a pair of arms movable between a tissue receiving configuration, in which distal ends thereof are separated from one another to receive a target tissue therebetween, and a tissue gripping configuration, in which the distal ends thereof are moved toward one another to grip the target tissue therebetween, proximal ends of the arms coupled to a control member slidably received within an outer sleeve so that movement of the control member relative to the outer sleeve moves the arms between the tissue receiving configuration and the tissue gripping configuration. The device also comprises a needle extending longitudinally from a proximal end to a distal end and including a first lumen extending longitudinally therethrough, the needle slidably received between the arms so that the needle is movable between a non-extended configuration, in which the distal end of the needle is proximal the distal ends of the arms, and an extended configuration, in which the distal end of the needle is distal of the distal end of the arms, a first suture element slidably received in the first lumen and deployable therefrom, the first suture element including a first cross member attached to distal end of a first suture, and a second suture element slidably received within the needle and deployable therefrom, the second suture element including a second cross member attached to a distal end of a second suture, wherein the first cross member is insertable into a first target tissue and the second cross member is insertable into a second target tissue so that coupling and tightening the first and second sutures to move the first and second cross members toward one another to approximate the first and second target tissue.

The present disclosure also relates to a method for treating a target tissue, comprising inserting a device to a target site in a living body, the device including a grasper including a pair of arms movable between a tissue receiving configuration and a tissue gripping configuration and a needle slidably received between the arms, moving the arms from the tissue receiving configuration to the tissue gripping configuration so that a first target tissue along a first side of a tissue defect is received between distal ends of the arms is gripped therebetween, sliding the needle distally with respect to the grasper, to an extended configuration, so that the distal end of the needle pierces the first target tissue gripped by the arms of the grasper, deploying a first suture element from the needle so that a first cross member of the first suture element is anchored in the first target tissue and a first suture of the first suture element extends proximally therefrom, moving the arms from the tissue receiving configuration to the tissue gripping configuration so that a second target tissue along a second side of the tissue defect is received between distal ends of the arms is gripped therebetween, and deploying a second suture element from the needle so that a second cross member of the second suture element is anchored in the second target tissue and a second suture of the second suture element extends proximally therefrom, and coupling and tightening the first and second sutures so that the first and second cross members are moved toward one another.

BRIEF DESCRIPTION

FIG. **1** shows a perspective view of a device according to an exemplary embodiment of the present invention;

FIG. **2** shows a perspective view of a grasper according to the device of FIG. **1**, in a tissue receiving configuration;

FIG. **3** shows a perspective view of the grasper according to the device of FIG. **1**, in a tissue gripping configuration;

FIG. **4** shows a perspective view of a needle extending through the grasper according to the device of FIG. **1**, the grasper in the tissue receiving configuration;

FIG. **5** shows a perspective view of the needle extending through the grasper according to the device of FIG. **1**, the grasper in the tissue gripping configuration;

FIG. **6** shows a perspective view of the needle according to the device of FIG. **1**;

FIG. **7** shows a longitudinal cross-sectional view of the needle according to the device of FIG. **1**;

FIG. **8** shows a perspective view of a T-tag suture according to the device of FIG. **1**;

FIG. **9** shows a side view of the device according to FIG. **1**, gripping and piercing a target tissue;

FIG. **10** shows a side view of the T-tag suture according to the device of FIG. **1**, anchored in the target tissue;

FIG. **11** shows a longitudinal side view of a grasper according to another exemplary embodiment of the present disclosure;

FIG. **12** shows a longitudinal side view of a grasper according to an alternate embodiment of the present disclosure;

FIG. **13** shows a side view of the T-tag suture according to the device of FIG. **1**;

FIG. **14** shows a side view of a T-tag suture according to another embodiment of the present disclosure;

FIG. **15** shows a side view of a T-tag suture according to yet another embodiment of the present disclosure;

FIG. **16** shows a side view of a T-tag suture according to another exemplary embodiment of the present disclosure;

FIG. **17** shows a side view of a T-tag suture according to yet another embodiment of the present disclosure;

FIG. **18** shows a side view of a T-tag suture according to another embodiment of the present disclosure;

FIG. **19** shows a perspective view of a grasper according to another embodiment of the present disclosure;

FIG. **20** shows another perspective view of the grasper according to FIG. **19**;

FIG. **21** shows a side view of the grasper according to FIG. **19**, in an open tissue receiving configuration; and

FIG. **22** shows a perspective view of the grasper according to FIG. **19**, in a closed tissue gripping configuration.

DETAILED DESCRIPTION

The present disclosure may be further understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same reference numerals. The present disclosure relates to devices for treating tissue and, in particular, relates to a tissue approximation and closure device. Exemplary embodiments of the present disclosure describe a tissue approximation and closure device comprising a grasper for grasping a target tissue and a needle extendable between arms of the grasper to pass suture t-tags through the target tissue grasped by the grasper. First and second portions of the suture T-tag may be inserted through first and second target portions of tissue, respectively, along opposing sides of a tissue defect, to approximate and close the tissue defect. It should be noted that the terms "proximal" and "distal" as used herein, are intended to refer to a direction toward (proximal) and away from (distal) a user of the device.

As shown in FIGS. **1-10**, a tissue approximation and closure device **100** according to an exemplary embodiment of the present disclosure comprises a grasper **102** including a pair of arms **104**, movable between a tissue receiving configuration and a tissue gripping configuration, and a needle **106** slidably received between the arms **104** of the grasper **102** so that the needle **106** may be inserted into target tissue gripped by the grasper **102**. A plurality of T-tag sutures **108** is slidably housed within the needle **106** so that the T-tag sutures **108** may be passed into the target tissue via the needle **106** as will be described in more detail below. Each T-tag suture **108** according to this embodiment includes a cross member **110** coupled to a length of suture **112** (FIG. **7**). In use, the grasper **102** is first used to grip a first portion of target tissue along a first side of a tissue defect. The needle **106** may then be advanced distally to penetrate the gripped tissue. When the needle **106** is positioned as desired with the needle **106** extending through the gripped tissue so that a distal tip thereof is on a distal side of the gripped tissue, a first T-tag suture **108** is then pushed out of the needle **106** to force the cross member **110** thereof into the first portion of target tissue with the suture **112** extending out of the first portion of target tissue on a proximal side of the tissue defect. After insertion of the first T-tag suture **108** into the first portion of target tissue, the needle **106** is retracted and the grasper **102** is opened to release the tissue. The grasper **102** is then repositioned to grip a second portion of target tissue, e.g., a portion along a second side of the tissue defect. When the grasper **102** has gripped the second portion of target tissue as desired, the needle **106** is again advanced distally to pass through the second portion of target tissue and a second T-tag suture **108** is pushed out of the needle **106** to lodge the cross member **110** thereof in the second portion of target tissue with its length of suture **112** extending through the second portion of target tissue on the proximal side of the tissue defect. The lengths of suture **112** attached to the first and second T-tag sutures **108** are then cinched or

tied to one another and tightened as desired in any other known manner to draw the first and second portions of target tissue into contact with one another to close the tissue defect. The grasper **102** may then be opened to release the second portion of target tissue and additional T-tag sutures **108** may be placed in a similar manner to more fully close the tissue defect and/or to close additional tissue defects as would be understood by those skilled in the art.

As would be understood by those skilled in the art, the grasper **102** and the needle **106** are coupled to a proximal portion (not shown) of the device **100** including, for example, a flexible member and a handle member facilitating the insertion of the grasper **102** and needle **106** to a target site within a living body. For example, the proximal portion may comprise a flexible sheath that houses the needle **106** and one or more control members for operating the grasper **102** so that the device **100** may be inserted through a working channel of an endoscope to target sites in the body. The handle member may include any known actuating mechanisms for actuating arms **104** of the grasper **102**, for moving the needle **106** and for deploying the T-tag suture **108**, as will be described in further detail below.

The grasper **102**, as shown in FIGS. **2-3**, comprises the pair of arms **104**, proximal ends **116** of which are connected to one another via an inner sleeve **118** slidably received within an outer sleeve **120**. The inner sleeve **118** extends from a proximal end (not shown) to a distal end **124** and includes a channel **126** extending therethrough. Proximal ends **116** of the arms **104** are connected to the distal end **124** of the inner sleeve **118** so that the arms **104** extend distally from opposing sides of the inner sleeve **118**. The inner sleeve **118** may be substantially tubular. Similarly, the outer sleeve **120** extends from a proximal end (not shown) to a distal end **128** and includes a channel **130** extending therethrough. The channel **130** of the outer sleeve **120** is sized and shaped to slidably receive the inner sleeve **118** therein. Thus, the inner and outer sleeves **118**, **120** may be slid longitudinally relative to one another to move the grasper **102** between the tissue receiving configuration, as shown in FIG. **2**, and the tissue gripping configuration, as shown in FIG. **3**. As would be understood by those skilled in the art, although the inner and outer sleeves **118**, **120** are described and shown as being substantially tubular, the inner and outer sleeves **118**, **120** may have any of a variety of shapes so long as the inner and outer sleeves **118**, **120** are coupled to be longitudinally movable relative to one another.

In one embodiment, the pair of arms **104** is biased toward the tissue receiving configuration, in which distal ends **114** thereof are separated from one another to receive target tissue therebetween, so that, when the inner sleeve **118** is moved proximally relative to the outer sleeve **120** drawing portions of the arms **104** into the sleeve **120**, an interior surface of the outer sleeve **120** contacts the arms **104** and draws them radially inward toward one another (i.e., toward the tissue gripping configuration). Each of the arms **104** extends from its proximal end **116** to its distal end **114** and is sized and shaped so that, when a proximal part of the arm **104** comes into contact with the interior surface of the outer sleeve **120**, the arm **104** is urged toward the tissue gripping configuration. In particular, each of the arms **104** in this embodiment includes a shoulder **122** shaped so that, when the inner sleeve **118** is drawn proximally into the outer sleeve **120**, an interior surface of the outer sleeve **120** engages an exterior surface of the shoulder **122** of each of the arms **104**, drawing the arms **104** together toward the tissue gripping configuration. When the inner sleeve **118** is moved distally relative to the outer sleeve **120**, the shoulder **122** extends distally beyond a distal end of the outer sleeve **120** extending the arms **104** out of the outer sleeve permitting the arms **104** to move apart according to their natural bias toward the tissue receiving configuration. The distal end **114** of each of the arms **104** in this embodiment extends laterally inward toward the distal end **114** of the other of the arms **104** to facilitate gripping of the target tissue. However, as would be understood by those skilled in the art, the distal end **114** may take any of a variety of shapes and may include any of a variety of gripping structures such as, for example, teeth, spikes, and/or other protrusions.

In yet another embodiment, not shown, the arms **104** may be moved between the tissue receiving and the tissue gripping configurations via a pull wire connected thereto. For example, the proximal ends **116** of the arms **104** may be pivotally coupled to the distal end **124** of the inner sleeve **118** with a distal end of the pull wire coupled to each of the arms **104** distally of this pivotal connection so that drawing the pull wire proximally relative to the inner sleeve **118** moves the arms **104** from the tissue receiving configuration to the tissue gripping configurations with distal movement of the pull wire relative to the inner sleeve **118** moving the arms **104** from the tissue gripping configuration to the tissue receiving configuration. It will be understood by those of skill in the art that, in this embodiment, an outer sleeve **120** is not required.

Although the above embodiments describe and show both of the arms **104** as being movable between the tissue receiving configuration and the tissue gripping configuration, in another embodiment, as shown in FIGS. **11-12**, a first one of the arms **104***a*' of a grasper **102**' is rigidly fixed at a proximal end **116***a*' thereof to a distal end **124**' of an inner sleeve **118**' while a second one of the arms **104***b*' is movable relative to the inner sleeve **118**'. The first one of the arms **104***a*' may extend along an axis substantially parallel to a longitudinal axis of the inner sleeve **118**'. The second one of the arms **104***b*' may be movably connected to the inner sleeve **118**' to move the grasper **102**' between a tissue receiving configuration, in which a distal end **114***b*' thereof extends away from the first one of the arms **104***a*', and a tissue gripping configuration, in which the distal end **114***b*' is moved toward the first one of the arms **104***a*'. In one example, as shown in FIG. **11**, the second one of the arms **104***b*' may be longitudinally movable with respect to the inner sleeve **118**' to move the grasper **102**' between the tissue receiving and gripping configurations. Specifically, the second one of the arms **104***b*' may be biased toward the tissue receiving configuration so that the second one of the arms **104***b*' may be drawn into the inner sleeve **118**' to move the grasper **102**' toward the tissue gripping configuration. In this embodiment, an outer sleeve is not necessary. In another example, as shown in FIG. **12**, the second one of the arms **104***b*' may be connected to the inner sleeve at a proximal end **116***b*' thereof via, for example, a pivotal connection. In this embodiment, an outer sleeve substantially similar to the outer sleeve **120** described above may be slidable over the inner sleeve **118**' to move the grasper **102**' between the tissue receiving and the tissue gripping configuration. The grasper **102**' may be used in a manner substantially similar to the clip **102**.

As shown in FIGS. **4-7**, the needle **106** is coaxially received within the channel **126** (FIG. **2**) of the inner sleeve **118** and is slidable therein between an extended configuration and a non-extended configuration. The needle **106** extends longitudinally from a proximal end to a distal end **132**. In the extended configuration, the distal end **132** of the needle **106** extends distally beyond the distal end **124** of the

inner sleeve **118** to pierce target tissue gripped between the distal ends **114** of the arms **104**. In the non-extended configuration, the needle **106** is withdrawn proximally with respect to the inner sleeve **118** so that the distal end **132** of the needle **106** is housed in the channel **126**. The needle **106** may be moved between the extended and non-extended configurations when, as shown in FIG. **4**, the grasper **102** is in the tissue receiving configuration, and when, as shown in FIG. **5**, the grasper **102** is in the tissue gripping configuration. The distal end **132** of the needle **106** may be sharpened or tapered to facilitate insertion of the needle **106** into target tissue as would be understood by those skilled in the art.

In one embodiment, as shown in FIG. **7**, the needle **106** may be a dual-slotted needle including a first lumen **134** and a second lumen **136** extending longitudinally therethrough. The first and/or second lumens **134**, **136** may be open to an exterior of the needle **106** along a portion of a length thereof. The first and second lumens **134**, **136**, however, are not required to be open to the exterior of the needle **106**, except at the distal end **132**. The first lumen **134** may house a first plurality of T-tag sutures **108** while the second lumen **136** houses a second plurality of T-tag sutures **108**. Each of the first and second lumens **134**, **136** is open at the distal end **132** so that the cross members **110** of the first and second pluralities of T-tag sutures may be deployed therefrom as described above.

In particular, a first actuating element **138** is received within the first lumen **134** proximally of a first one of the cross members **110** and a second actuating element **140** is received within the second lumen **136** proximally of the second one of the cross members **110**. Thus, when it is desired to insert one of the T-tag sutures **108**, a corresponding one of the first and second actuating elements **138**, **140** is moved distally with respect to the needle **106** to deploy the desired a T-tag suture **108** from one of the first and second pluralities thereof. The first and second actuating elements **138**, **140** may be configured as rods or other longitudinal members suitable for pushing the cross members **110** and the corresponding sutures **112** from the first and second lumens **134**, **136**, respectively. Although only a single pair of T-tag sutures **108** is described, it will be understood by those of skill in the art that the needle **106** may be configured to house any number of T-tag suture's **108** in the first and second lumens **134**, **136**, respectively. In particular, each of the first and second lumens **134**, **136**, respectively, may house a plurality of cross members **110** in line therewithin with the respective suture lengths **112** trailing proximally therefrom.

In another embodiment, not shown, the needle **106** may include a single lumen with multiple T-tag sutures **108** contained in line therein. The T-tags **108**, however, may be housed within the needle **106** in any of a variety of configurations, so long as each of the T-tag sutures **108** may be applied to treat tissue, as will be described in more detail below.

As shown in FIG. **8**, each of two T-Tag sutures **108** includes a cross member **110** and a length of suture **112**. As described above, the sutures **112** of the two T-tag sutures **108** may be cinched, tied or otherwise coupled or connected to one another to approximate separated portions of tissue and/or to close a tissue defect. Specifically, each of the lengths of suture **112** extends from a proximal portion **150** to a distal end **152** attached to the cross member **110**. The cross member **110** may be configured as an elongated element movably or rotatably connected to the distal end **152** of the suture **112** so that the cross member **110** is movable between an insertion configuration in which the cross member **110** is substantially parallel to the suture **112** and an anchoring configuration in which the cross member **110** is transverse to the suture **112** in, for example, a substantially T-shaped configuration.

The cross members **110** of the T-tag sutures **108** are housed within the first and second lumens **134**, **136**, respectively, of the needle **106** in the insertion configuration. Upon deployment from a respective one of the first and second lumens **134**, **136** into target tissue, the cross members **110**, are rotated to the T-shaped configuration anchoring the T-tag sutures **108** in the tissue into which they have been inserted. The cross members **110** may be biased toward the T-shaped configuration or may simply revert to this position when tension is applied to the corresponding suture **112** and contact with the surrounding tissue urges the cross members to extend transverse to the direction in which the tension is applied (i.e., along the suture **112**).

As shown in FIG. **13**, T-tag sutures **108** of one exemplary embodiment may further include a cinching element **154** movable distally over its suture **112** to capture and couple to the suture **112** of another T-tag suture **108** to enable a user to draw the sutures of the two T-tag sutures **108** toward one another and to lock them in a desired position relative to one another thereby constraining the portions of tissue within which the respective cross members **110** are embedded to remain in a desired spatial relation relative to one another (e.g., held in contact with one another to seal a tissue defect). Once the cinching element **154** has been moved to a desired position along the sutures **112**—i.e., a desired level of approximation has been achieved between the portions of target tissue—the cinching element **154** may be crushed or otherwise deformed to fix the cinching element **154** in the desired position along the sutures **112**. In another example, as shown in FIG. **14**, T-tag sutures **108'** may be substantially similar to the T-tag sutures **108**, comprising a cinching element **154'**. Sutures **112'** of the T-tag sutures **108'**, however, includes barbs **156'** or teeth extending therealong to act as a ratchet so that the cinching element **154'** may be moved therealong to a desired position as discussed above and so that the ratchet action between the cinching element **154'** automatically locks the sutures **112'** together as desired. Thus, the cinching element **154'** is not required to be crushed or deformed to fix the cinching element **154'** in a desired position along the sutures **112'**.

In another example, as shown in FIG. **15**, T-tag sutures **108"** are substantially similar to the T-tag sutures **108**, **108'**, but do not require a cinching element. Rather, sutures **112"** thereof may be knotted together to fix the cross members **110"** thereof at a desired distance relative to one another. In one embodiment, a knot **154"** may be tied by a user after the cross members **110"** have been applied to the tissue as desired. In another embodiment, the knot **154"** may be moved along the sutures **112"** so that drawing proximal ends of the sutures **112"** proximally pushes the knot **154"** distally along the sutures **112"** to draw the cross members **110"** of the two T-tag sutures **108"** toward one another.

Although the above embodiments show and describe identical T-tag sutures **108**, **108'**, **108"** applied to each of the first and second target tissues, it is also possible to insert different T-tag sutures into each of the first and second target tissues, so long as anchoring portions (e.g., cross members) of each of the T-tag sutures inserted into each of the first and second target tissue may be drawn toward one another to approximate the portions of tissue into which they are inserted.

In one example, as shown in FIG. **16**, a first T-tag suture **208***a* may be inserted into a first target tissue along a first

side of a tissue defect while a second T-tag suture **208***b* may be inserted into a second target tissue along a second side of the tissue defect. The first T-tag suture **208***a* may be substantially similar to the T-tag sutures described above, comprising a cross member **210***a* at a distal end **252***a* of a suture **212***a*. A proximal end **250***a* of the suture **212***a*, however, includes a loop **254***a* or other opening through which a length of a suture **212***b* of the second T-tag suture **208***b* may be received. In particular, the second T-tag suture **208***b* may be substantially similar to the T-tag suture **108'** described above, comprising a cross member **210***b* and a suture **212***b*, the suture **212***b* including barbs **256***b* or teeth extending along a length thereof. The length of the suture **212***b* is passed through the loop **254***a* so that, when the suture **212***b* of the second T-tag suture **208** is drawn proximally, the first and second anchor portions **210***a*, **210***b* of the first and second T-tag sutures **208***a*, **208***b*, respectively, are drawn toward one another. The barbs **256***b* engage the opening of the loop **254***a*, acting as a ratchet so that the suture **212***b* may be drawn proximally through the loop **254***a*, but is prevented from being moved distally therethrough. Thus, drawing the suture **212***b* approximates the first and second target tissue in which the cross members **210***a*, **210***b* of the first and second T-tag sutures **208***a*, **208***b*, respectively, are inserted, while also maintaining the desired level of approximation. The suture portion **212***b* may include multiple barbs **256***b* or teeth, as shown in FIG. **16**, to allow the cross members **210***a*, **210***b* to be positioned at varying distances relative to one another, or, as shown in FIG. **17**, may include a single barb **256***b*, tooth or other enlargement so that the cross members **210***a*, **210***b* may be fixed with respect to one another at a predetermined distance.

In another example, as shown in FIG. **18**, a T-tag suture **308** includes a first cross member **310***a* and a second cross member **310***b* connected to one another via a single length of suture **312**. In particular, the first cross member **310***a* is connected to a first end **352** of the suture **312**. The second cross member **310***b* includes a pair of holes extending laterally therethrough. The suture **312** is threaded through the pair of holes so that, in an anchoring configuration, the cross member **310***b* extends transverse to the suture **312** in a substantially T-shaped configuration. Thus, when the cross members **310***a*, **310***b* are inserted into first and second target tissues, respectively, drawing a second end **350** of the suture **312** proximally causes the suture **312** to slide through the pair of holes of the second cross member **310**, shortening a length of suture **312** extending between the first and second cross members **310***a*, **310***b*. The first and second target tissues, in which the first and second cross members **310***a*, **310***b* are inserted, are thereby approximated. The T-tag suture **308** may also include a cinch **354** which extends about overlapping portions of the suture **312** so that, when the second cross-member **310***b* is inserted into the second target tissue, the cinch **354** extends on a proximal side of the second target tissue. Once a desired level of approximation has been achieved, the cinch **354** may be positioned against a proximal surface of the second target tissue and deformed or crushed to fix the cinch **354** in the desired position along the suture **312** to maintain the desired level of approximation. Alternatively, the cinch **354** may be configured so that the proximal end **350** of the suture **312** may be drawn proximally relative thereto, but is prevented from being moved distally relative thereto. For example, portions of a length of the suture **312** may include teeth, barbs or other protrusions for acting as a ratchet mechanism. In another example, a force required to slide the suture **312** through the cinch **354** may be greater than any tension along a portion of the suture **312** extending between the first and second cross-members **310***a*, **310***b*, when the first and second cross members **310***a*, **310***b* are used to approximate tissue.

The above described T-tag sutures are exemplary only. It will be understood by those of skill in the art that the device **100** may include any of a variety of suture mechanisms so long as the T-tag sutures include anchoring portions such as, for example, cross members, which may be anchored or inserted into portions of tissue so that the portions of tissue into which they have been anchored may be moved toward one another via the suture mechanism.

In use, a distal portion of the device **100**, including the grasper **102** and the needle **106**, may be inserted into a target site within a living body via, for example, a working channel of an endoscope. The device **100** may be inserted with the grasper **102** in a closed, tissue gripping configuration and the needle **106** in the non-extended configuration. Once the device **100** is at the target site, the grasper **102** may be opened from the tissue gripping configuration to the tissue receiving configuration so that a first target tissue **12** along a first side of a tissue defect **10** may be received between the arms **104** of the grasper **102**. The grasper **102** may then be moved toward the tissue gripping configuration so that the first target tissue **12** is gripped by the distal ends **114** of the arms **104**. As shown in FIG. **9**, the needle **106** may then be moved distally relative to the grasper **102** toward the extended configuration so that the distal end **132** pierces the first target tissue **12**, passing through the first target tissue **12** past a distal surface **14** thereof. The first one of the T-tag sutures **108** may then be deployed from the needle **106** by, for example, pushing the first actuating element **138** distally with respect to the first lumen **134**. As the cross member **110** extends distally past the distal end **132** of the needle **106**, the cross member **110** is moved from the insertion configuration toward the T-shaped anchoring configuration. Thus, when the grasper **102** is moved toward the tissue receiving configuration to release the first target tissue **12** and the needle **106** is withdrawn therefrom toward the non-extended configuration, the first of the T-tag sutures **108** remains anchored to the first target tissue **12**.

The grasper **102** may then be moved toward a second target tissue **16** along a second side of the tissue defect and positioned so that the second target tissue is received between the arms **104**. The first and second target tissue **12**, **16** may extend along opposing sides of the tissue defect **10**. The arms **104** are then moved toward the tissue gripping configuration so that the second target tissue **16** is gripped between the distal ends **114** thereof. Similarly to the first target tissue **12**, the needle **106** may then be moved from the non-extended configuration toward the extended configuration so that the distal end **132** of the needle **106** pierces the second target tissue **16**. A second one of the T-tag sutures **108** may then be applied to the second target tissue **16**, the cross member **110** being moved toward the T-shaped anchoring configuration as it is released from the needle **106**, as shown in FIG. **10**. Thus, the second of the T-tag sutures **108** remains anchored to the second target tissue **16** even when the grasper **102** is opened to release the second target tissue and the needle **106** is withdrawn toward the non-extended configuration. Once the T-tag sutures **108** have been applied to the first and second target tissue, sutures **112** of each of the T-tag sutures **108** are drawn toward one another by, for example, cinching, knotting or any other coupling mechanism. The cinching, knotting and/or coupling of the sutures **112** approximates the first and second portions of target tissue **12**, **16** and also maintains the tissue defect **10** in this closed configuration.

Although the method above describes the deployment of one pair of T-tag sutures **108**, as described above, the needle **106** of the device **100** may house a plurality of pairs of T-tag sutures **108**. Thus, additional pairs of T-tag sutures **108** may be applied, without having to remove the device **100** to reload the device **100** with additional T-tag sutures **108**, as desired or necessary. For example, additional T-tag sutures **108** may be applied along a length of the tissue defect until the entire tissue defect is closed.

As shown in FIGS. **19-22**, a grasper **402** according to another exemplary embodiment may be utilized in the device **100** in a manner substantially similar to the grasper **102**. Similarly to the grasper **102**, the grasper **402** includes arms **404** which may be coupled to a distal end of an inner sleeve (not shown). The arms **404** may be moved between an open tissue receiving configuration and a closed tissue gripping configuration by, for example, moving an outer sleeve **420** longitudinally with respect to the inner sleeve. Distal ends **414** of each of the arms **104**, however, include a gripping element **460** which, when the arms **404** are moved toward the tissue gripping configuration, form an opening **466** through which the needle **106** may be extended. For example, each gripping element **460** may include protrusions **464** extending laterally inward from opposing longitudinal edges **462** of each arm **404**. In one embodiment, the protrusions **464** may be curved to form a substantially semi-circular gripping element **460** so that, when the arms **404** are moved toward the tissue gripping configuration, the gripping elements **460** of the arms **404** may together form a substantially cylindrical shape. Thus, when the needle **106** is moved toward the extended configuration, the needle **106** extends between the distal ends **414**, through the opening **466** of the cylinder formed via the gripping elements **460**. Gripping edges **468** of each of the gripping elements **460** may include teeth, spikes, or other similar gripping structures for enhancing the grip of target tissue between the distal ends **414**.

It will be apparent to those skilled in the art that various modifications may be made in the present disclosure, without departing from the scope of the disclosure.

What is claimed is:

1. A device for treating a tissue defect, comprising:

a grasper including a pair of arms movable between a tissue receiving configuration, in which distal ends thereof are separated from one another to receive tissue therebetween, and a tissue gripping configuration, in which the distal ends thereof are moved toward one another to grip tissue therebetween, each of the arms including a shoulder adjacent to a proximal end thereof;

a needle extending longitudinally from a proximal end to a distal end and including a first lumen extending longitudinally therethrough, the needle slidably received between the arms so that the needle is movable between a non-extended configuration, in which the distal end of the needle is proximal to the distal ends of the arms, and an extended configuration, in which the distal end of the needle is distal of the distal end of the arms; and

a first suture element slidably housed within the first lumen and deployable therefrom to be anchored in a first target tissue into which the first suture element is inserted, the first suture element including a first cross member attached to a distal end of a first suture,

wherein the grasper further includes an inner sleeve extending from a proximal end to a distal end and including a channel extending therethrough, the proximal ends of the arms are connected to the distal end of the inner sleeve on opposing sides thereof,

wherein, when the inner sleeve moves proximally, the arms move toward the tissue gripping configuration, and

wherein the grasper further includes an outer sleeve slidably receiving the inner sleeve and extending from a proximal end to a distal end, the outer sleeve including a channel extending therethrough, each of the shoulders of the arms being shaped so that, as the inner sleeve is drawn proximally into the outer sleeve, an interior surface of the outer sleeve engages an exterior surface of each of the shoulders, drawing the arms together toward the tissue gripping configuration.

2. The device of claim **1**, wherein the arms are biased toward the tissue receiving configuration.

3. The device of claim **1**, further comprising a second suture element to be anchored in a second target tissue, the second suture element including a second cross member attached to a distal end of a second suture.

4. The device of claim **3**, further comprising a cinch slidable along a length of the first and second sutures to move the first and second cross members toward one another and approximate the first target tissue and the second target tissue.

5. The device of claim **3**, wherein at least one of the first and second sutures includes one of teeth and barbs along a length thereof.

6. The device of claim **5**, wherein another one of the first and second sutures includes an opening for engaging one of the teeth and barbs.

7. The device of claim **3**, wherein the needle further comprises a second lumen extending longitudinally therethrough, the second suture element received within the second lumen of the needle.

8. The device of claim **7**, wherein one of the first and second lumens are open to an exterior of the needle along a length thereof.

9. The device of claim **1**, wherein the first suture element is movable between an insertion configuration, in which the first cross member is substantially aligned along a length of the first suture, and an anchoring configuration, in which first cross member extends transverse to the length of the first suture.

10. The device of claim **1**, wherein the distal ends of the grasper arms include distal tips extending laterally inward toward one another to grip tissue therebetween.

11. The device of claim **1**, wherein the distal ends of the grasper arms include a gripping structure which, when the arms are in the tissue gripping configuration, form an opening extending therethrough so that the needle, in the extended configuration, passes through the opening.

12. The device of claim **1**, wherein gripping edges of the distal ends of the arms include one of teeth, spikes and protrusions for gripping tissue received between the distal ends of the arms.

13. The device of claim **1**, wherein the arms move into the tissue receiving configuration upon moving distally away from the outer sleeve.

14. A device for approximating edges of a tissue defect, comprising:

a grasper including a pair of arms movable between a tissue receiving configuration, in which distal ends thereof are separated from one another to receive a target tissue therebetween, and a tissue gripping configuration, in which the distal ends thereof are moved toward one another to grip the target tissue therebe-

tween, each of the arms including a shoulder adjacent to a proximal end thereof, the proximal ends of the arms coupled to an inner sleeve slidably received within an outer sleeve so that movement of the inner sleeve relative to the outer sleeve moves the arms between the tissue receiving configuration and the tissue gripping configuration;

a needle extending longitudinally from a proximal end to a distal end and including a first lumen extending longitudinally therethrough, the needle slidably received between the arms so that the needle is movable between a non-extended configuration, in which the distal end of the needle is proximal to the distal ends of the arms, and an extended configuration, in which the distal end of the needle is distal of the distal end of the arms;

a first suture element slidably received in the first lumen and deployable therefrom, the first suture element including a first cross member attached to a distal end of a first suture; and

a second suture element slidably received within the needle and deployable therefrom, the second suture element including a second cross member attached to a distal end of a second suture, wherein the first cross member is insertable into a first target tissue and the second cross member is insertable into a second target tissue so that coupling and tightening of the first and second sutures will move the first and second cross members toward one another to approximate the first and second target tissue,

wherein the outer sleeve slidably receiving the inner sleeve and extending from a proximal end to a distal end, the outer sleeve including a channel extending therethrough, each of the shoulders of the arms being shaped so that, as the inner sleeve is drawn proximally into the outer sleeve, an interior surface of the outer sleeve engages an exterior surface of each of the shoulders, drawing the arms together toward the tissue gripping configuration.

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